OCT 2 5 2000

Section I

510(k) Summary
Required by 21 CFR §807.92

I. Submitter:

A. Name: Medisystems Corporation

B. Address: 1201 Third Avenue
Seattle, WA 98101-3016

C. Phone and Fax Numbers: Phone: 206-621-6500
Fax 206-621-6501

D. Contact Person: Mr. Fredric Swindler

II. Date of preparation of this Summary: August 1, 2000

III. Trade name: Access Alert™ Gauge

IV. Common name: Hemodialysis System Accessory

V. Classification name: Hemodialysis System and Accessories

VI. The marketed device(s) to which equivalence is claimed: The Medisystems Access Pressure Manometer that is the subject of this submission is substantially equivalent to the Baxter SPS 550 Hemodialysis Machine marketed by Baxter Healthcare Corporation, Renal Division and described in 510(k) number K901038.

VII. Product description: The device consists of an aneroid manometer with flexible connecting tube that when attached to the female Luer of an AV fistula needle equipped with a filtered connector allows measurement of static arterial and/or venous pressures in a vascular access such as a fistula or graft.

VIII. Statement of intended use compared to currently marketed predicate device: The Medisystems Access Pressure Manometer, (Access Alert Gauge™), is used with an Arterial Venous Fistula Needle equipped with a filtered connector to measure static arterial and/or venous inter-access pressures. This is equivalent to the pressure monitoring function of the Baxter SPS 550 Hemodialysis Machine.

IX. Discussion of technological characteristics: There are no new technological characteristics inherent in the device which would affect its safety or effectiveness. The device is a mechanical aneroid manometer which is used to monitor static inter-access arterial and venous pressure.

X. Safety and effectiveness: To assure that the device is safe and effective, all finished products are tested and must meet all required release specifications before distribution. The testing required for release includes, but is not limited to; physical testing and visual examination of the finished product.

The required testing is defined by written and approved procedures that conform to the product design specifications. This testing for the Medisystems Access Pressure Manometer is defined in detail in the "Device Master Records."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 5 2000

Mr. Fredric G. Swindler
Vice President
Quality Assurance and Regulatory Affairs
Medisystems Corporation
1201 Third Avenue
39th Floor
Seattle, WA 98101-3016

Re: K002372
Access Alert Gauge™
Dated: August 1, 2000
Received: August 4, 2000
Regulatory Class: II
21 CFR §876.5820/Procode: 78 KOC

Dear Mr. Swindler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Section A

510(k) Number (if known): K002372

Device Name: Medisystems Access Pressure Manometer

Indications For Use:

The Medisystems Access Pressure Manometer, (Access Alert Gauge™), is used with an Arterial Venous Fistula Needle equipped with a Medisystems Access Alert filtered connector to measure static arterial and/or venous inter-access pressures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Optional Format 1-2-96)

David A. Lagrow

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002372